MAR 2 2 2001

510 (k) Summary

1. **Submitter's name, Address and Contact Person**

Submitter: EMD, Electronic Medical Devices, Corp.
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Tel: (305) 534 9594 - Fax: (305) 674 4454 - Email: emdcorp@altavista.com

Contact Person: Jean Claude Marty

Date: September 27, 2000

2. **Name of the Device:** K.E.A.T.®

3. **Name of Predicate Devices:** Innova system by EMPI, Inc. (K941911)
Incare Stimulation Probe by Hollister (K891773)

4. **Description of Device**

The K.E.A.T. is composed of two parts: a vaginal Applicator-Stimulator and its carrying and control case, without cable linking one to the other.

1) The vaginal Applicator-Stimulator is adapted to be inserted into any woman's vagina to stimulate electrically the pelvic floor musculature. It contains 2 ring-shaped electrodes and one ring-shaped conductor positioned on the exterior of the plastic body, a rechargeable battery and a electronic circuit inside the applicator. Between each use it is kept in its resting nest of the carrying and control case in order to preserve it and to recharge its inside battery. Before to be used it is prepared from the carrying and control case according to the type of incontinence, the selected duty cycle, and the wished use time.

2) The carrying and control case contains a transformer with charge circuitry, an electronic control system, 3 control knobs (type of incontinence, duty cycle, and time treatment), a charge control light and three metal contacts in the resting nest of the Applicator-Stimulator. These metal contacts permit to charge the rechargeable 6 volts lithium-ion battery, which is inside the vaginal applicator-stimulator, and to transmit instructions to the inside vaginal Applicator-Stimulator electronic circuit.

5. **Intended Use**

The K.E.A.T. is a pelvic floor muscle stimulation device, for home use, designed to assist female patient to treat symptoms of Stress Incontinence, Urge Incontinence and Mixed Incontinence (a combination of Stress and Urge Incontinence).

6. Statement of Technological Characteristics of the Device.

COMPARISON OF THE K.E.A.T. TO PREDICATE DEVICES

Design:

Innova system by EMPI, Inc. (K941911)	**K.E.A.T.**
- Dual channel system stimulates motor and sensory responses to treat both stress and Urge symptoms	- Dual channel system stimulates motor and sensory responses to treat both stress and urge symptoms.
- Unit consists of separate pack attached to electrode.	- Rechargeable battery is contained in the Applicator-Stimulator.
- Unit operates from a standard 9 volts alkaline battery.	- Unit operates with a 6 volts rechargeable lithium-ion battery.
- Indicator light displays ON/OFF status for each channel.	- Charge control light displays charge or ready to use status.
- Stimulator belt clip allows patient mobility during treatment.	- Unit is self-contained with no limitation on mobility.
- N/A	- 110/220 battery charge transformer inside the carrying and control case.
- Channel 1 and 2 control knobs.	- Stress and Urge incontinence control knobs
- Duty Cycle selector: - 5 seconds ON, 5 seconds OFF - 5 seconds ON, 10 seconds OFF	- Duty Cycle selector: - 5 seconds ON, 5 seconds OFF - 5 seconds ON, 10 seconds OFF

Physical & Electrical Characteristics:

Innova system by EMPI, Inc. (K941911)	**K.E.A.T.**
- Output Type Current: nominally constant current up to 1 kΩ	- Output Type Current: nominally constant current up to 1 kΩ
- Intensity: Normal output balanced symmetrical bisphasic 0 to +/- 100 mA	- Intensity: Normal output balanced symmetrical biphasic 0 to +/- 100 mA
- Pulse width: 300 micro seconds	- Pulse width: 300 micro seconds
- Rate: Ch 1: 50 Hz, Ch 2: 12.5 Hz	- Rate: Stress Incontinence: 50 HZ Urge Incontinence: 12.5 Hz
- Timing Control: Continuous (C) Normal Operation (R); 15 min, 30 min.	- Timing Control: 15 min, 30 min.
- Duty Cycle: 1) ON: 5 sec., OFF: 5 sec. 2) ON: 5 sec., OFF: 10 sec.	- Duty Cycle: 1) ON: 5 sec., OFF: 5 sec. 2) ON: 5 sec., OFF: 10 sec.
- Power Source: 9 volts alkaline battery	- Power Source: 6 volts rechargeable lithium-ion battery
- Expected battery life: Continuous mode 60 mA setting = 4.0 hours. Normal cycling mode 60 mA setting = 8.0 hours	- Expected battery life: N/A (Rechargeable battery),

Materials:

Incare Stimulation Probe by Hollister (K891773)	**K.E.A.T.**
- Body applicator materials: Acrylonitrile-Butadiene-Styrene copolymer (ABS)	- Body Applicator-Stimulator materials: Acrylonitrile-Butadienne-Styrene copolymer (ABS)
- Electrodes Material: Stainless steel	- Electrodes and Conductor Material: Stainless steel

Size of the Electrodes

Incare Stimulation Probe by Hollister (K891773)	**K.E.A.T.**
- Diameter 1 inch (2.54 cm)	- Diameter 2.50 cm
- Length of the Generating line 3/8 of inch (0.9525 cm)	- Length of the Generating line 1 cm
- Surface area of each electrode 1.1781 inch^2 = 7.601 cm^2	- Surface area of each electrode 7.854 cm^2

7. Biocompatibility

The materials of the applicator-stimulator of the K.E.A.T. which contact the patient are exactly the same that the materials of the Vaginal Stimulation Probe (K891773) by Hollister.

Body Material: Acrylonitrile-Butadiene-Styrene copolymer (ABS)

Electrode Material: Stainless steel

Conductor Material: Stainless steel

8. Conclusion

Based upon the information presented above it is concluded that the K.E.A.T. is safe and effective for its intended use and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2001

Mr. Jean Claude Marty
President
EMD, Electronic Medical Devices, Corp.
1621 Bay Road, Suite #908
MIAMI BEACH FL 33139-3260

Re: K002154
EMD K.E.A.T.® (Kegel Exercises Alternative Trainer)
Dated: January 8, 2001
Received: January 11, 2001
Regulatory Class: II
21 CFR §876.5320/Procode: 78 KPI

Dear Mr. Marty:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K002154/A1

510(k) NUMBER (IF KNOWN): K002154

DEVICE NAME: K.E.A.T.

INDICATIONS FOR USE:

The K.E.A.T. is a pelvic floor muscle stimulation device, for home use, designed to assist female patients to treat symptoms of:

- Stress Incontinence,
- Urge Incontinence,
- Mixed Incontinence (a combination of Stress and Urge Incontinence).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002154